K122269

DEC 13 2012

510(k) Summary

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- Date Prepared.....September 19, 2012

- Trade/Device Name: Enamic®
- Common Name: Dental CAD/CAM Block
- Classification Name: Porcelain Powder for Clinical Use (21 CFR 872.6660, Product Code: EIH)
- Secondary Classification Name: Tooth Shade Resin Material (21 CFR 872.3690, Product Code: EBF)

Predicate Devices: Vitablocs® 510(k) 102128 and
Lava Ultimate CAD/CAM Restorative for Cerec/ E4D,
Lava Ultimate Implant Crown Restorative 510(k) 110131

Device Description

The Vita Enamic® block consists of interpenetrating networks of ceramic and polymer material to form a solid block of material. The unique marriage of the two materials creates a dual-network hybrid, which lends the positive physical properties of each individual material to the other. This results in a material with significantly lower brittleness of a pure ceramic and better abrasion behavior than a pure resin, (similar to natural enamel). The material is milled in a dental CAD/CAM machine into its restorative form.

Statement of Intended Use:

Enamic® is indicated for use as a dental restoration including inlays, onlays, veneers, and crowns.

Substantial Equivalence

Information provided in this application shows that the product is substantially equivalent to the predicate devices. The blending of these two proven dental materials creates beneficial physical properties while continuing to remain compliant to the ISO standards applied to these material types. Comparisons of the physical properties of the Enamic to the predicate devices are included in this application.

Technological Characteristics

Design

The geometry of the Enamic block is the same as the predicate Vitabloc.. Both blocks have an attachment, called a mandrel, which is used to secure it into a CAD/CAM machine for milling into its final form. Both blocks are polished and ready for placement thereafter.

Material

The majority volume of the Enamic block is made up of the exact same material as the Vitabloc predicate: feldspar. The remaining volume of the block is made up of resin. This combination of feldspar and resin material is similar to the Lava Ultimate predicate. Comparisons of the material composition to the two predicates to the Enamic are included in this application.

An assessment of the biocompatibility of the new device was performed, based on FDA Recognized ISO 10933 and ISO 7405 standards. This assessment, included in this application, concluded that the device is safe for its intended use.

Summary of Non-Clinical Performance Data

Bench testing was performed in accordance to FDA recognized standards ISO 10477 and ISO 6872. The results of this testing allowed us to conclude that Enamic is safe and effective for its intended use. Test results are included in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 13, 2012

Vita Zahnfabrik H. Rauter GmbH & Company
C/O Ms. Elizabeth Wolfsen
Regulatory Affairs Specialist
Vident
3150 East Birch Street
BREA CA 92821

Re: K122269
Trade/Device Name: Enamic®
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH, EBF
Dated: November 12, 2012
Received: December 5, 2012

Dear Ms. Wolfsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

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Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122269

Device Name: Enamic®
Indications for Use:

Enamic® is indicated for use as a dental restoration including inlays, onlays, veneers, and crowns.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.11 15:05:11 -05'00'

(Division Sign Off)
Division of Dental, Infection Control and General Hospital Devices

510(k) Number

Prescription Use _____ OR Over-The-Counter Use_____
(Par. 21 CFR 801.109